II. REMARKS

Reconsideration of the present application in view of the following remarks is respectfully requested.

A. Status of the claims

Claims 8-11, 13-14, 16, 20, 22-24, 29-30, 32-38 and 40-49 are currently pending. New claims 46-49 have been added. Support for new claim 46 can be found in the original application as filed, e.g., in the original claims and at page 11, lines 21-27. Support for new claims 47-49 can be found in the Examples of the original application as filed, e.g., in Examples 5, 7, 10 and 12. It is respectfully submitted that no new matter has been added by virtue of the present amendment.

B. Rejection under 35 U.S.C. § 103 over Kogan et al.

Claims 8-11, 13, 14,16, 20, 22-24, 29, 30, 32-38 and 40-45 were rejected under 35 U.S.C. § 103(a) on the grounds of being unpatentable over U.S. Patent No. 4,910,205 to Kogan et al ("the Kogan patent"). In the Office Action, the Examiner stated that the "recitation of [the] in-vitro test does not impart patentability to claims directed to method of treating allergic rhinitis or claims directed to transdermal device applied to patients to provide specific plasma levels of loratadine, i.e. in vivo use."

This rejection is respectfully traversed. While the Valia-Chien cell was known to one skilled in the art, the prior art is absolutely silent about the claimed relative release rates as determined by the Valia-Chien cell. In fact, the prior art of record does not even apply the Valia-Chien cell to transdermal delivery systems containing loratatine. Applicants respectfully submit that the relative release rates are "functional limitation[s] [that] must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used... ." MPEP 2173.05(g).

In the Office Action, the Examiner admits that the Kogan patent "...does not teach the specific delivery profile of loratadine, the specific amounts of different

ingredients, or specific solvents and softening agents in the transdermal delivery system." See page 4, lines 5-7 of the Office Action. Accordingly, Applicant's respectfully disagree with the Examiner's later position that "it is expected to have the same delivery profile from a transdermal delivery device disclosed by the prior art that has the same composition and the same amount or loratadine."

Applicants further submit that the Examiner is relying on impermissible hindsight vision in reconstructing the present invention. The Examiner states that it is "within the skill in the art to select optimal parameters in order to achieve a beneficial effect" and to "adjust the dose to deliver a desired plasma profile." However, the Examiner has not provided motivation to one skilled in the art to treat a patient with a device which provides the specific relative release rates and the specific blood plasma level range recited in the present claims. Therefore, as the Examiner has not provided motivation to manipulate the prior art in order to arrive at the present claims, Applicants respectfully request that the obviousness rejection over the Kogan patent be withdrawn.

The Examiner is requested to separately consider the patentability of new claim 46, which recites in part, "...a reservoir layer consisting essentially of 20 to 90% by weight of a polymeric matrix, 0.1 to 30% by weight of a softening agent, 0.1 to 20% by weight of loratadine base or of a pharmaceutically acceptable salt thereof and 0.1 to 30% by weight of a solvent for the loratadine or salt thereof... ." (Emphasis Added)

B. Rejection under 35 U.S.C. § 103 over Kogan et al in view of Hille et al.

Claims 37, 38, 44 and 45 were rejected under 35 U.S.C. § 103(a) on the grounds of being unpatentable over the Kogan patent in view of U.S. Patent No. 5,240,711 to Hille et al.

This rejection is traversed as Applicants respectfully submit that Hille et al. fail to cure the deficiencies of the Kogan patent as discussed above. Therefore, the Examiner is respectfully requested to remove the present rejection.

III. CONCLUSION

In view of the foregoing, Applicants believe that all claims are now in condition for allowance. The Examiner is invited to contact the undersigned by telephone if a telephone interview would advance prosecution of the present application. An early and favorable action is earnestly solicited.

Respectfully submitted,
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